

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : **Confirmation No. 3058**
Horst Georg ZERBE et al. : **Docket No. 2004-0189**
Serial No. 10/771,388 : **Group Art Unit 1616**
Filed February 5, 2004 :

WATER SOLUBLE FILM FOR ORAL
ADMINISTRATION WITH
INSTANT WETTABILITY

THE COMMISSIONER IS AUTHORIZED
TO CHARGE ANY DEFICIENCY IN THE
FEE FOR THIS PAPER TO DEPOSIT
ACCOUNT NO. 23-0975.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of ☒ the references listed on attached form PTO-1449 and/or ☐ the additional information identified below in paragraph 3. A legible copy of each reference listed on the form PTO-1449 is enclosed.

1a. ☒ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, **or**

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

and thus no certification and/or fee is required.

1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

(1) ☐ the certification of paragraph 2 below is provided, **or**

(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

the certification of paragraph 2 below is provided, and

the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

2. It is hereby certified

a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or

b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.


3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☐ a full or partial English language translation submitted herewith,
 - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
 - c. ☐ the concise explanation contained in the specification of the present application at page,
 - d. ☒ the concise explanation set forth in the attached English language abstract,
 - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☐ A foreign patent office search report citing one or more of the references is enclosed.

Respectfully submitted,

Horst Georg ZERBE et al.

By:



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May 5, 2004

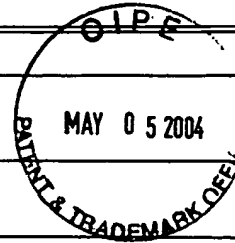
FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)
(Use several sheets if necessary)

Date Submitted to PTO: May 5, 2004

ATTY DOCKET NO.
2004-0189SERIAL NO.
10/771,388APPLICANT
Horst Georg ZERBE et al.FILING DATE
February 5, 2004

GROUP



U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	6,592,887	7/2003	Zerbe et al.			
	AB	6,552,024	4/2003	Chen et al.			
	AC	6,489,341	12/2002	Jerussi			
	AD	6,436,407	8/2002	Clements et al.			
	AE	6,342,496	1/2002	Jerussi et al.			
	AF	6,335,023	1/2002	Yu et al.			
	AG	6,264,981	7/2001	Zhang et al.			
	AH	5,955,098	9/1999	Dugger, III			
	AI	5,952,382	9/1999	Bernardon			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO	
	AJ	02/085119	10/2002	WO				
	AK	00/42992	7/2000	WO				
	AL	03/030883	4/2003	WO				
	AM	01/03917	1/2001	WO				
	AN	02/02085	1/2002	WO				

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AO	Patent Abstracts of Japan for JP 58-059910, published April 9, 1983.
	AP	Patent Abstracts of Japan for JP 03-246220, published November 1, 1991.
	AQ	Patent Abstracts of Japan for JP 03-209327, published September 12, 1991.

EXAMINER

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U.S. PATENT DOCUMENTS

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	AA	5,871,905	2/1999	Thieme et al.			
	AB	5,853,740	12/1998	Lu et al.			
	AC	5,824,334	10/1998	Stanley et al.			
	AD	5,785,989	7/1998	Stanley et al.			
	AE	5,414,005	5/1995	Schneider et al.			
	AF	5,147,654	9/1992	Place et al.			
	AG	4,764,378	8/1988	Keith et al.			
	AH	5,629,003	5/1997	Horstmann et al.			
	AI	2003/0118653	6/2003	Chen et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO	
	AJ	02/066016	8/2002	WO				
	AK	00/10539	3/2000	WO				
	AL	03/026654	4/2003	WO				
	AM	03/015748	2/2003	WO				
	AN	01/30288	5/2001	WO				

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AO	Patent Abstracts of Japan for JP 03-209326, published September 12, 1991.
	AP	Patent Abstracts of Japan for JP 63-310818, published December 19, 1988.
	AQ	Patent Abstracts of Japan for JP 62-135417, published June 18, 1987.

EXAMINER

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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	2003/0099690	5/2003	Awamura et al.			
	AB	5,565,466	10/1996	Gioco et al.			
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO	
	AJ	01/07507	2/2001	WO				
	AK	1 391 212	2/2004	Europe				
	AL	0 781 546	3/2001	Europe				
	AM	0 526 524	12/995	Europe				
	AN	1 103 253	5/2001	Europe				

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AO	
	AP	
	AQ	

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of form with next communication to applicant.

List of documents for the Information Disclosure Statement

US Patent Application No. 10/771,388
Horst Georg ZERBE et al.

Publication No.	Priority	Publication	Title
Abstract. (Only if document has a priority earlier than 11/1996)			
US 6,592,887 B2	11/1996	7/2003	Water soluble film for oral administration with instant wettability
US 6,552,024 B1	1/1999	4/2003	Compositions and methods for mucosal delivery
US 6,489,341 B1	1/1999	12/2002	Methods for the treatment of neuroleptic and related disorders using sertindole derivatives
US 6,436,407 B1	8/1994	8/2002	Mutant enterotoxin effective as a non-toxic adjuvant
US 6,342,496 B1	3/1999	1/2002	Bupropion metabolites and methods of use
US 6,335,023 B1	6/1999	1/2002	Oligosaccharide aldonic acids and their topical use
US 6,264,981 B1	10/1999	7/2001	Oral transmucosal drug dosage using solid solution
US 5,955,098 A	4/1996	9/1999	Buccal non polar spray or capsule
US 5,952,382 A	5/1995	9/1999	Adamantyl-substituted retinoids and pharmaceutical/cosmetic compositions comprised thereof
US 5,871,905 A	9/1996	2/1999	Reduction of false positives in oral-fluid based immunoassays
US 5,853,740 A	8/1996	12/1998	Delivery system for pharmaceutical agents encapsulated with oils

US 5,824,334 A	9/1989	10/1998	Tobacco substitute
US 5,785,989 A	5/1985	7/1998	Compositions and methods of manufacturing of oral dissolvable medicaments
US 5,783,207 A	5/1985	7/1998	Selectively removable nicotine-containing dosage form for use in the transmucosal delivery of nicotine
US 5,565,466 A	8/1993	10/1996	Methods for modulating the human sexual response
US 5,414,005 A	10/1993	5/1995	Methods and articles of manufacture for the treatment of nicotine withdrawal and as an aid in smoking cessation
US 5,147,654 A	7/1990	9/1992	Oral osmotic device for delivering nicotine
US 4,764,378 A	2/1986	8/1988	Buccal drug dosage form
WO 02/085119 A	4/2001	10/2002	Intraoral Delivery of Nicotine for Smoking Cessation
WO 00/42992 A	1/1999	7/2000	Compositions and Methods for Mucosal Delivery
WO 03/30883 A	10/2001	4/2003	Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions
WO 01/03917 A	7/1999	1/2001	Multilayered Film Containing an Active Substance and made of Cross-linked Hydrophilic Polymers
WO 02/2085 A	7/2000	1/2002	Rapidly-Decomposing Administrable Form for Releasing Active Ingredients in the Oral Cavity or in Bodily Cavities

WO 02/66016 A	2/2001	8/2002	Mucoadhesive Dispersible Pharmaceutical Preparation for Active-Agent Dosing in Veterinary and Human Medicine
WO 00/10539 A	8/1998	3/2000	Active Ingredient Support in the Form of a Film
US 5,629,003 A	6/1990	5/1997	Rapidly Disintegrating Sheet-Like Presentations of Multiple Dosage Units
WO 03/26654 A	9/2001	4/2003	Nicotine-Containing Film Preparation
WO 03/15748 A	8/2001	2/2003	Mucoadhesive Erodible Drug Delivery Device for Controlled Administration of Pharmaceuticals and other Active Compounds
US20030118653A	6/2001	6/2003	Quick Dissolving Oral Mucosal Drug Delivery Device with Moisture Barrier Coating
WO 99/17753 A	10/1997	4/1999	Rapidly Soluble Filmy Preparation
WO 01/30288 A	10/1999	5/2001	Oral Transmucosal Drug Dosage using Solid Solution
WO 01/07507 A	7/1999	2/2001	Pullulan Film Compositions
US 4,900,552 A	3/1988	2/1990	Mucoadhesive Buccal Dosage Forms
WO 02/87622 A	4/2001	11/2002	Oral Preparations and Supports for Oral Preparations
EP 1 103 253 A	11/1999	5/2001	Aqueous Film Coating Agent and Oral Solid Preparation

EP 781 546 B1	12/1995	7/1997	A Multi-Layered Film Preparation
EP 526 524 B1	4/1990	2/1993	Pharmaceutical Compositions
JP 03/246220 A	2/1990	11/1991	Film Pharmaceutical Preparation Adherent to Mucus Membrane in Oral Cavity
JP 03/209327 A	1/1990	9/1991	Nicotine-Containing Cataplasm for Oral Cavity Membrane
JP 03/209326 A	1/1990	9/1991	Nicotine-Containing Cataplasm for Oral Cavity Membrane
JP 63/310818 A	6/1987	12/1988	Sheet Preparation to be Applied to Oral Mucosa
JP 62/135417 A	12/1985	6/1987	Filmy Pharmaceutical
JP 58/059910 A	10/1981	4/1983	Manufacturing of Film Preparation Adhesive to Mucous Membrane